5.4 CYANTRANILIPROLE (263)

RESIDUE AND ANALYTICAL ASPECTS

Cyantraniliprole was initially evaluated for toxicology and residues by the JMPR in 2013 and an ADI of 0–0.03 mg/kg bw was established. An ARfD was considered to be unnecessary. Additional use patterns were evaluated by the 2015 JMPR. The residue definitions established in 2013 and maintained at the 2015 JMPR are:

Definition of the residue for compliance with the MRL for both plant and animal commodities: *cyantraniliprole.*

Definition of the residue for dietary risk assessment for unprocessed plant commodities: *cyantraniliprole.*

Definition of the residue for dietary risk assessment for processed plant commodities: *sum of cyantraniliprole and IN-J9Z38, expressed as cyantraniliprole.*

Definition of the residue for dietary risk assessment for animal commodities: *sum of cyantraniliprole, 2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-3,4-dihydro-3,8-dimethyl-4-oxo-6-quinazolinecarbonitrile [IN-J9Z38], 2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1Hpyrazol-5-yl]-1,4-dihydro-8-methyl-4-oxo-6-quinazolinecarbonitrile [IN-MLA84], 3-Bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2-(hydroxymethyl)-6-[(methylamino)carbonyl]phenyl]-1H-pyrazole-5-carboxamide [IN- N7B69] and 3-Bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2[[(hydroxymethyl)amino]carbonyl]-6-methylphenyl]-1H-pyrazole-5-carboxamide [IN-MYX98],expressed as cyantraniliprole*

The residue is not fat-soluble.

At the Forty-ninth Session of the CCPR (2017), cyantraniliprole was scheduled for evaluation of additional use patterns by the 2018 JMPR.

The Meeting received a soil degradation study in rice, various supervised residue trial data for foliar and soil applications of cyantraniliprole on grapes, strawberries (outdoor), cranberries (outdoor), mango (outdoor), cucumber (glasshouse), and paddy rice and information on registered uses of cyantraniliprole on corresponding crops. In addition a processing study on grapes was resubmitted.

Environmental fate

In a supervised residue trial on rice, the degradation of cyantraniliprole and its metabolite IN-J9Z38 was investigated at three sites. A single application of 150 g ai/ha was sprayed over the rice paddies. Soil, plant and water samples were taken at various intervals ranging from 1 hour to 60 days after application.

The calculated half lives in water ranged from 2.0–6.2 days for cyantraniliprole (n = 3) and 10.3 days (one site only) for IN-J9Z38. The calculated half lives in plants ranged from 3.2–6.3 days for cyantraniliprole (n = 3). No residue of IN-J9Z38 was detected in the plant samples at any time point and no half-life could be calculated. The calculated half-life in soil was 6.8 days for cyantraniliprole (n = 1). No residue of parent or IN-J9Z38 was detected in any of the other soil samples at any time point.

Parent cyantraniliprole and metabolite IN-J9Z38 are not persistent in soil/water systems.

Methods of analysis

The methods for analysing cyantraniliprole and metabolites IN-F6L99, IN-J9Z38, IN-JCZ38, IN-K7H19, IN-MLA84, IN-MYX98, IN-N5M09, and IN-N7B69 as previously evaluated (2013 Meeting) were supported with additional recovery data from supervised trials. The methods are considered valid for the commodities evaluated

Stability of pesticide residues in stored analytical samples

The stability of residues of cyantraniliprole and its metabolites in stored samples was covered by the freezer stability studies evaluated by the 2013 JMPR. Additional storage stability data on cranberries were submitted and support the conclusions on storage stability from previous Meetings. Analysis of the samples from the residues trials and processing studies submitted for the current Meeting are sufficiently covered.

Results of supervised residue trials on crops

The Meeting received supervised trials data for cyantraniliprole on grapes (field), strawberries (greenhouse and field), cranberries (field), mango (field), cucumber (glasshouse), and paddy rice (field).

The Meeting noted that GAPs have been authorised for the use of cyantraniliprole and the product labels were available from Belgium, Cambodia, Canada, China, the United Kingdom, and the USA.

For the estimation of maximum residue levels and STMRs, the 2018 Meeting also used data from the 2013 and 2015 JMPR evaluations.

Wine grapes

The critical GAP for cyantraniliprole on wine grapes is from Italy with 2 foliar applications of 112.5 g ai/ha, a re-treatment interval of 14 days and PHI of 10 days.

Only four trials conducted in the 2014 growing season, conducted in Europe and evaluated by the current Meeting, matched this GAP. European trials conducted in the 2009/2010 growing seasons evaluated by the 2013 JMPR and additional trials from the 2014 season could be matched using the proportionality principle.

Cyantraniliprole residues from trials matching GAP without applying proportionality are (n = 27): 0.031, 0.058, 0.070, 0.071, 0.096, 0.099, 0.11, 0.14, 0.14, 0.16, 0.18, 0.19, 0.21, 0.24, 0.28, 0.30, 0.33, 0.34, 0.40, 0.41, 0.42, 0.43, 0.48, 0.64, 0.67, 0.68 and 0.80 mg/kg.

Scaling factors applied ranged from 0.74–1.0.

Scaled residues were (n = 27): 0.30, 0.054, 0.059, 0.068, 0,090, 0,099, 0.11, 0.11, 0.12, 0.15, 0.16, 0.18, 0.18, <u>0.21</u>, 0.22, 0.23, 0.24, 0.32, 0.34, 0.40, 0.42, 0.42, 0.45, 0.50, 0.53, 0.59, and 0.75 mg/kg.

The Meeting estimated a maximum residue level of 1.0 mg/kg and a STMR of 0.21 mg/kg for wine grapes on the basis of the critical GAP from Italy.

Table grapes

The critical GAP for table grapes was from Belgium where the GAP for both table and wine grapes consists of 2 foliar applications of 53 g ai/ha, a re-treatment interval of 10 days and a PHI of 10 days.

As no trials matched this GAP the Meeting did not estimate a maximum residue level for table grapes.

Cranberries

The critical GAP for cyantraniliprole on cranberries is from Canada and comprises 3 foliar applications of 150 g ai/ha, a re-treatment interval of 7 days with a PHI of 14 days.

Five trials conducted in the 2009 growing season in Canada and the USA matched this GAP. The resulting residues were (n = 5): < 0.01, 0.010, 0.012, 0.030, and 0.041 mg/kg.

The Meeting estimated a maximum residue level for cyantraniliprole of 0.08 mg/kg and a STMR value of 0.012 mg/kg for cranberries.

Strawberries

The critical GAP for cyantraniliprole on strawberries is the GAP from Canada (field) with 3 foliar applications of 150 g ai/ha, a re-treatment interval of 5 days and a PHI of 1 day. Residue levels in trials from Canada and the USA matching this GAP were (n = 8): 0.086, 0.20, 0.22, 0.27, 0.64, 0.64, 0.70, and 0.84 mg/kg.

Based on the USA/Canadian data set the Meeting estimated a maximum residue level for cyantraniliprole of 1.5 mg/kg and a STMR value of 0.455 mg/kg for strawberries.

Mango

The critical GAP for cyantraniliprole on mangoes is the Cambodian GAP which comprises 2 foliar applications of 180 g ai/ha, with a re-treatment interval of 7 days and a PHI of 7 days.

Eight trials performed in the 2017 growing season in Thailand and Vietnam matched this GAP. The resulting residues in the RAC (whole fruit with stone and peel) were (n = 8): 0.035, 0.064, 0.064, 0.086, 0.11, 0.12, 0.18, and 0.45 mg/kg.

Residues in the edible portion (mango pulp) for dietary risk assessment were (n = 8): < 0.01 (7) and 0.028 mg/kg.

The Meeting estimated a maximum residue level for cyantraniliprole of 0.7 mg/kg and a STMR value of 0.01 mg/kg for mango.

Cucurbits, cucumbers - Greenhouse

The 2013 Meeting recommended a maximum residue level of 0.3 mg/kg for fruiting vegetables, cucurbits, based on outdoor uses on cucumber, summer squash and melons. The current Meeting received labels from Canada and the USA for the use of cyantraniliprole on greenhouse grown cucumbers.

The critical greenhouse GAP for cyantraniliprole on cucumbers is the GAP in the USA which comprises 3 foliar applications of 150 g ai/ha, a re-treatment interval of 5 days and a PHI of 0 days.

Five trials performed in the 2010 growing season in the USA (evaluated by the 2015 JMPR) matched this GAP. The resulting residues were (n = 5): 0.032, 0.043, 0.18, 0.19 and 0.33 mg/kg. However, five trials were considered insufficient to estimate a maximum residue level for a major crop.

An alternate GAP for greenhouse grown cucumbers submitted to the current Meeting is the Canadian GAP of 4 × 100 g ai/ha, a RTI of 7 days, and a PHI of 0 days. Only four greenhouse trials from Europe (2013 JMPR) could be matched to this GAP. The number of trials was considered insufficient for the estimation of a maximum residue level for cucumbers.

The trials from Europe could not be matched to the USA GAP using the "GAP versus trial" model introduced by the 2017 Meeting either, as the model estimated the residue levels to be 29% lower than the GAP in the European trials.

The Meeting decided to withdraw its previous recommendation for "Fruiting vegetables, cucurbits" of 0.3 mg/kg, based on outdoor uses, and to replace it with a maximum residue level 0.3 mg/kg for the "Group of Fruiting vegetables, Cucurbits".

Rice

Residue trials on rice evaluated by the 2013 Meeting could not be matched to the GAP from Vietnam (50–100 g ai/ha, PHI 5 days) submitted in 2013. The 2018 Meeting received a new label for a use on rice in China for 2 spray applications at 60 g ai/ha, with a re-treatment interval of 7 days and a PHI of 21 days.

Supervised residue trials conducted in the 2010 and 2011 growing season in China (JMPR 2013), did not match the GAP submitted to the current Meeting.

However, residues in husked rice in overdosed trials conducted with 2 or 3 × 100 g ai/ha, RTI 7 days and a PHI of 21 days were all < 0.01 mg/kg (n = 12). In trials using 2 or 3 × 150 g ai/ha, RTI 7 days and PHI 21 days residues ranged from < 0.01 (9) to 0.019 mg/kg (n = 12). The data suggested a residue below LOQ at the critical GAP.

The Meeting concluded that residues above LOQ are not anticipated, when applied according to GAP and estimated a maximum residue level for cyantraniliprole of 0.01(*) mg/kg and a STMR value of 0.01 mg/kg for rice, husked. As residues in husked rice were below LOQ and residues in polished rice are expected to be even less, the Meeting decided to apply the estimations for husked rice to polish rice.

Cereal and grass forages, straws and hays

Rice straw

The supervised trials data were available for rice straw from China.

Overdosed trials conducted with 2 (n = 6) or 3 (n = 6) × 100 g ai/ha, RTI 7 days and a PHI of 21 days could be matched to the Chinese GAP by applying proportionality. The trials using different application rates were performed at the same location and were considered replicate trials. The highest residue level after scaling was selected per site. Unscaled cyantraniliprole residues in rice straw from trials matching the critical GAP were (n = 6): 0.075 (2), 0.17, 0.18, 0.4, and 1.9 mg/kg.

Scaling factors ranging from 0.4–0.6 were applied, resulting in scaled residues of (n = 6): 0.030, 0.045, <u>0.068</u>, <u>0.11</u>, 0.24, and 0.76 mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg (1.7 mg/kg dry weight) for cyantraniliprole in rice straw. The Meeting estimated median residue level of 0.089 mg/kg (0.099 mg/kg dry weight assuming 90% DM) and a highest residue of 0.76 mg/kg (0.84 mg/kg dry weight assuming 90% DM) for rice straw.

Miscellaneous

Rice hulls

The same trials as for rice were considered for rice hulls. Overdosed trials conducted with 2 (n = 6) or 3 (n = 6) × 100 g ai/ha, RTI 7 days and PHI of 21 days could be matched to this GAP by applying proportionality. The trials using different application rates were performed at the same location and were considered replicate trials. The highest residue level after scaling was selected per site. Unscaled cyantraniliprole residues in rice straw from trials matching the critical GAP were (n = 6): 0.32, 0.57, 0.95, 1.5, 1.6, and 2.3 mg/kg.

Scaling factors ranging from 0.4–0.6 were applied, resulting in scaled residues of (n = 6): 0.19, 0.34, <u>0.38</u>, <u>0.60</u>, 0.96 and 1.4 mg/kg.

The Meeting estimated a median residue level of 0.49 mg/kg (0.54 mg/kg dry weight assuming 90% DM) for rice hulls.

Residues in processed commodities

Processing studies were undertaken for grapes and were evaluated by the 2013 Meeting. STMR-Ps were derived by the current Meeting.

Commodity	PF Residue: parent + IN-J9Z38	PF median [a]	STMR-RAC	STMR-P
Grape				
- must	0.79, 1.5, 1.6	1.5	0.21	0.32
- juice	0.48, 0.52, 1.4	0.52	0.21	0.11
- wine (bottled)	0.5, 1.0, 1.2	1.0	0.21	0.21
- raisin	0.48, 0.52, 2.3	0.52	[b]	[b]
- wet pomace	1.4, 2.7, 3.9	2.7	0.21	0.57

[a] Values were taken from the 2013 evaluation.

[b] The Meeting did not estimate a STMR-P for raisins, since the labels refer to wine-grapes only.

Residues in animal commodities

Farm animal dietary burden

The 2018 Meeting evaluated residues in grapes (pomace) and rice (hulls, grain and straw), which were listed in the OECD feeding table in addition to dietary burden calculated in 2015. The Meeting noted that the estimation did not result in a significant change to the dietary burdens of farm animals; a maximum increase of 9.6% of the maximum dietary burden was observed. The previous recommendations of maximum residue levels for animal commodities were maintained.

RECOMMENDATIONS

On the basis of the data from supervised residue trials the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI assessment.

Definition of the residue for compliance with the MRL for both plant and animal commodities: *cyantraniliprole.*

Definition of the residue for dietary risk assessment for unprocessed plant commodities: *cyantraniliprole.*

Definition of the residue for dietary risk assessment for processed plant commodities: *sum of cyantraniliprole and IN-J9Z38, expressed as cyantraniliprole.*

Definition of the residue for dietary risk assessment for animal commodities: *sum of cyantraniliprole, 2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-3,4-dihydro-3,8-dimethyl-4-oxo-6-quinazolinecarbonitrile [IN-J9Z38], 2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1Hpyrazol-5-yl]-1,4-dihydro-8-methyl-4-oxo-6-quinazolinecarbonitrile [IN-MLA84], 3-Bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2-(hydroxymethyl)-6-[(methylamino)carbonyl]phenyl]-1H-pyrazole-5-carboxamide [IN- N7B69] and 3-Bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2[[(hydroxymethyl)amino]carbonyl]-6-methylphenyl]-1H-pyrazole-5-carboxamide [IN-MYX98],expressed as cyantraniliprole*.

The residue is not fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for cyantraniliprole is 0–0.03 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for cyantraniliprole were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the 2013, 2015 and 2018 JMPR. The results are shown in Annex 3 of the 2018 JMPR Report. The IEDIs ranged from 4–40% of the maximum ADI.

The Meeting concluded that long-term dietary exposure to residues of cyantraniliprole from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The 2013 JMPR decided that an ARfD for cyantraniliprole was unnecessary. The current Meeting therefore concluded that the acute dietary exposure to residues of cyantraniliprole from the uses considered is unlikely to present a public health concern.